IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: COLOPLAST CORP.
PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION — MDL NO. 2387

THIS DOCUMENT RELATES TO:

Christine Cabellero v. Coloplast Corp. — *Civil Action No. 2:14-cv-18347*

MEMORANDUM OPINION & ORDER

Pending before the court is Coloplast Corp.'s Motion to Dismiss on the Pleadings [ECF No. 11]. The plaintiff responded [ECF No. 16] and Coloplast Corp. replied [ECF No. 17] making the Motion ripe for adjudication. For the reasons set forth below, the Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 500 of which are in the Coloplast Corp. ("Coloplast") MDL, MDL 2387.

On August 22, 2000, Ms. Caballero[1] was surgically implanted with Coloplast's Suspend-Tutoplast Processed Fascia Lata ("Fascia Lata"), a device manufactured by

[1] The plaintiff advises that although the case is styled as Cabellero, her correct surname is Caballero. *See* Am. Short Form Compl. ¶ 1 [ECF No. 2].

Coloplast to treat SUI and to reconstruct the pelvic floor. Am. Short Form Compl. ¶¶ 9–10 [ECF No. 2]. Ms. Caballero's surgery occurred at St. Petersburg General Hospital in St. Petersburg, Florida. *Id.* ¶ 11. Ms. Caballero claims that as a result of implantation of the Fascia Lata, she has experienced multiple complications. She adopts the following counts as alleged in the First Amended Master Long Form Complaint and Jury Demand ("Master Complaint"): I – negligence, II – strict liability design defect, III – strict liability manufacturing defect, IV – strict liability failure to warn, V – strict liability defective product, VI – breach of express warranty, VII – breach of implied warranty, VIII –fraudulent concealment, IX – constructive fraud, X – discovery rule and tolling, XI –negligent misrepresentation, XII – negligent infliction of emotional distress, XIII – violation of consumer protection laws, XIV – gross negligence, XV – unjust enrichment, and XVII – punitive damages. *Id.* ¶ 13.

According to the Master Complaint, Coloplast "designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products," one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23 [ECF No. 49, MDL 2387]. Coloplast admits in its Joint Master Long Form Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint and Jury Demand ("Master Answer") that it "generally packaged, labeled, marketed, sold[,] and distributed" such pelvic mesh devices. Master Answer ¶ 22 [ECF No. 62, MDL 2387]. The Fascia Lata device is "dehydrated, . . . processed fascia lata from donated human tissue." *See* Def.'s Mot. Dismiss on the Pleadings Ex. B, at 1 [ECF No. 11-2] ("Package Insert"). The Fascia Lata is preserved such that it

"retains the three-dimensional collagen structure responsible for the unidirectional, mechanical properties of the original fascia lata tissue." *Id.*

II. Legal Standard

"[T]he Rule 12(c) judgment on the pleadings procedure primarily is addressed to . . . dispos[e] of cases on the basis of the underlying substantive merits of the parties' claims and defenses as they are revealed in the formal pleadings." 5C Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1367 (3d ed. 2004). A motion under 12(c) is useful when only questions of law remain. *Id.*

> [A] Rule 12(c) motion is designed to provide a means of disposing of cases when the material facts are not in dispute . . . and a judgment on the merits can be achieved by focusing on the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense . . . .

Id. Rule 12(h)(2) provides that the defense of failure to state a claim upon which relief can be granted may be raised in a motion for judgment on the pleadings. Fed. R. Civ. P. 12(h)(2). If this is asserted in a Rule 12(c) motion, the district court will apply the same standards for granting the appropriate relief or denying the motion as it would have employed had the motion been brought prior to the defendant's answer under 12(b)(6). Wright & Miller, *supra*, § 1367; *see Exec. Risk Indem., Inc. v. Charleston Area Med. Ctr., Inc.*, 681 F. Supp. 2d 694, 706 n.17 (S.D. W. Va. 2009) ("[T]he standards under Federal Rule of Civil Procedure 12(c) for a motion for judgment on the pleadings are identical to those applicable to a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss.").

A motion to dismiss filed under Rule 12(b)(6) tests the legal sufficiency of a complaint or pleading. *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). A pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). To achieve facial plausibility, the plaintiffs must plead facts allowing the court to draw the reasonable inference that the defendant is liable, moving the claim beyond the realm of mere possibility. *Id.* Mere "labels and conclusions" or "formulaic recitation[s] of the elements of a cause of action" are insufficient. *Twombly*, 550 U.S. at 555.

III. Discussion

The plaintiff asserts that Coloplast's Rule 12(c) Motion to Dismiss on the Pleadings is truly a Rule 56 Summary Judgment Motion because Coloplast has attached exhibits for the court's consideration. However, when deciding a 12(c) motion, the court may consider "the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense." Wright & Miller, *supra*, § 1367. Of Coloplast's attached documents and the plaintiff's referenced evidence in their

Response, the court will only consider the package insert marked as Exhibit B to Coloplast's Motion because it is integral to the claim for relief and defense. *See* Package Insert. The package insert offers a product description and a warranty statement which are pertinent to the claims at hand—specifically the breach of warranty claims. *See id.* at 1; Am. Short Form Compl. ¶ 13.

The evidence the plaintiff puts forward in her Response, the content from Coloplast's website, is not part of the content of the pleadings, an exhibit thereto, incorporated by reference in the pleadings, or central or integral to the claims. Therefore, it will not be considered. *See* Response [ECF No. 16]. Coloplast's Exhibits C, D, E, & F, the plaintiff's medical records and Plaintiff Profile Form, will not be considered for the same reasons. *See* Def.'s Mot. Dismiss on the Pleadings Ex. C [ECF No. 11-3]; Def.'s Mot. Dismiss on the Pleadings Ex. D [ECF No. 11-4]; Def.'s Mot. Dismiss on the Pleadings Ex. E [ECF No. 11-5]; Def.'s Mot. Dismiss on the Pleadings Ex. F [ECF No. 11-6]. Further, Coloplast attached the Amended Short Form Complaint as Exhibit A to its Motion. *See* Def.'s Mot. Dismiss on the Pleadings Ex. A [ECF No. 11-1]. This *is* a pleading and must be considered by the court, and accordingly has no transformative power. Thus, Coloplast's Motion is not a Rule 56 Summary Judgment Motion.

Next, this court applies the substantive tort law of the state where the plaintiff's implantation occurred—in this case, Florida. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-760, 2016 WL 3067752, at *2 (S.D. W. Va. May 31, 2016); Am. Short Form Compl. ¶ 11. The claims are addressed below.

a. Strict Liability and Breach of Warranty (Counts II–VII)

Coloplast argues that it is immune from the plaintiff's strict liability and warranty claims alleged in Counts II-VII by virtue of Florida's human tissue shield statute which states:

> The procurement, processing, testing, storing, or providing of human tissue and organs for human transplant, by an institution qualified for such purposes, is the rendering of a service; and such service does not constitute the sale of goods or products to which implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques.

Fla. Stat. Ann. § 672.316(6). No reported cases address this section of the Florida Code. However, Florida has an analogous blood shield provision in the same section that provides:

> The procurement, processing, storage, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body for any purpose whatsoever is declared to be the rendering of a service by any person participating therein and does not constitute a sale, whether or not any consideration is given therefor; and the implied warranties of merchantability and fitness for a particular purpose are not applicable.

Fla. Stat. Ann. § 672.316(5). The Supreme Court of Florida opined that § 672.316(5)

> created a "blood shield" statute within Florida's Uniform Commercial Code for the purpose of eliminating actions for strict liability against blood banks. Section 672.316(5) was enacted to limit the Uniform Commercial Code warranties in the context of the sale of blood by declaring such a sale to be a "service."

Silva v. S.W. Fla. Blood Bank, Inc., 601 So. 2d 1184, 1188 (Fla. 1992) (citations omitted). Additionally, the Supreme Court of Florida has stated that the "blood shield" statute aligned Florida with the majority of jurisdictions, making "the

handling of blood . . . a service not subject to strict liability as opposed to a sale." *Rostocki v. S.W. Fla. Blood Bank, Inc.*, 276 So. 2d 475, 476 (Fla. 1973).

Notably, the United States District Court for the Middle District of Florida, relying primarily on public policy, narrowed *Silva* and found that the *Silva* decision barred strict liability and warranties claims only against blood banks—not against pharmaceutical companies. *Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467, 1482 (M.D. Fla. 1993) ("[T]he Supreme Court of Florida in *Silva* . . . stated unequivocally that § 672.316(5) was enacted to eliminate actions for strict liability against blood banks and to limit U.C.C. warranties in the context of the sale of blood by blood banks. . . . The Supreme Court of Florida clearly did not state that § 672.316(5) was also enacted . . . to convert failure-to-warn products liability claims against pharmaceutical manufacturers into ordinary negligence claims.), *aff'd in part, rev'd in part on other grounds sub nom. Christopher v. Cutter Labs.*, 53 F.3d 1184 (11th Cir. 1995).

It is clear that the "blood shield" statute, § 672.316(5), bars strict liability and warranties claims. Because the language of the human tissue shield statute is analogous in this respect, I find that § 672.316(6) similarly bars those claims. The question then remains, against whom these claims are barred. A notable distinction between the two statutes is the use of the language "by an institution qualified for such purposes" in § 672.316(6), and its absence in § 672.316(5). This difference is especially important because § 672.316(6) was adopted after § 672.316(5), indicating that the legislature contemplated a different application scheme. *See* Fla. Stat. Ann.

§ 672.316 (West Supp. 1984). Moreover, this difference demonstrates that I am not bound by the *Walls* decision's narrow application of the "blood shield" statute. *See Walls*, 832 F. Supp. at 1482. Plainly, "an institution qualified for such purposes" is broad and consequently should not be constrained to human tissue banks or any other particular entity. Coloplast is an institution qualified to distribute human tissue devices and so is covered by the plain language in § 672.316(6).

Additionally, public policy mandates the same conclusion. Where the statutory language varies modestly between jurisdictions, the public policy behind blood and human tissue shield statutes remains the same. On this matter, the California Court of Appeal stated:

> [L]egislatures have determined that the production and use of human blood and its derivatives for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally.

Cryolife, Inc. v. Super. Ct., 2 Cal. Rptr. 3d 396, 405 (Cal. Ct. App. 2003) (emphasis omitted) (quoting *Hyland Therapeutics, Inc. v. Super. Ct.*, 220 Cal. Rptr. 590, 594 (Cal. Ct. App. 1985)). Moreover, there is "a nationwide antipathy over applying products-liability or strict-liability concepts to body parts such as blood and tissue." *Palermo v. Lifelink Found., Inc.*, 152 So. 3d 1177, 1181 (Miss. Ct. App. 2014); *see also* 63 Am. Jur. 2d *Products Liability* § 625 (2010) ("An action for products liability may be brought under several theories, including . . . strict liability, and warranty."). Indeed, "no court has ever applied strict liability to the distribution of human tissue."

Condos v. Musculoskeletal Transplant Found., 208 F. Supp. 2d 1226, 1229 (D. Utah 2002); *see Palermo*, 152 So. 3d at 1181.

According to the Master Complaint, Coloplast "designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products," one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23. Coloplast admits in its Master Answer that it "generally packaged, labeled, marketed, sold[,] and distributed" such pelvic mesh devices. Master Answer ¶ 22. Thus, it is not in dispute that Coloplast distributed the Fascia Lata allograft. Per its labeling, the allograft is "dehydrated, Tutoplast processed Fascia [L]ata from donated human tissue." Package Insert 1. The plaintiff does not dispute this fact either. Because there is no dispute as to whether Coloplast distributed processed human tissue, the Fascia Lata, no discovery is needed to determine whether the statute applies, as the plaintiff suggests. Coloplast's actions are plainly covered by the statute and must be considered a "service." Public policy, precedent, and the plain language of § 672.316(6) all dictate that the plaintiff's strict liability and breach of warranty claims must fail.

The plaintiff further argues that discovery is needed to identify other conduct that may allow a claim for strict liability to go forward. It is well-settled law, however, that the scope of discovery may not exceed the boundaries of the complaint. *See Cuomo v. Clearing House Ass'n, LLC*, 557 U.S. 519, 531 (2009) ("Judges are trusted to prevent 'fishing expeditions' or an undirected rummaging through . . . records for evidence of some unknown wrongdoing.").

Therefore, Counts II–VII of the plaintiff's Amended Short Form Complaint, which correspond with Counts II–VII in the Master Complaint, are **DISMISSED with prejudice**.

b. Remaining Claims (Counts I, VIII–XV, XVII)

Coloplast argues that the plaintiff's remaining claims are time barred. The court declines to consider the plaintiff's medical records as they are outside the scope of the Rule 12(c) standard. Additionally, the plaintiff has not plead adequate facts to determine whether her claim is statutorily barred. This matter is appropriate for a Rule 56 summary judgment motion; currently, it is not grounds for dismissal.

Given the plaintiffs' Steering Committee's impending motion to amend the Master Complaint contemplated in the plaintiff's Response, the nature of a short form complaint, and for reasons appearing to the court, the Motion is **DENIED** at this time as to all other claims (Counts I, VIII–XV, XVII).

IV. Conclusion

For the reasons stated above, it is **ORDERED** that Coloplast's Motion to Dismiss on the Pleadings [ECF No. 11] is **GRANTED in part** and **DENIED in part**. The Motion is **GRANTED** with respect to Counts II–VII and is otherwise **DENIED** at this time. Counts II–VII are **DISMISSED with prejudice**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 22, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE